

Exhibit 60

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

DONALD CHAIRES, GEORGE
DENAULT, JANE DOE, JOHN DOE,
BRITTANY GILLELAND, GERALD
GIRARD, SARA HASSELBACH,
LINDSEY KINHAN, JOSEPH
MCLAUGHLIN, MARILYN PERSON,
MATTHEW TEACHMAN, and KARYN
WOFFORD,

Plaintiffs,

v.

NOVO NORDISK INC., ELI LILLY AND
COMPANY, and SANOFI U.S.,

Defendants.

Civil Action No.

**COMPLAINT and
DEMAND FOR JURY TRIAL**

Plaintiffs Donald Chaires, George Denault, Jane Doe, John Doe, Brittany Gilleland, Gerald Girard, Sara Hasselbach, Lindsey Kinhan, Joseph McLaughlin, Marilyn Person, Matthew Teachman, and Karyn Wofford, on behalf of themselves and all others similarly situated, for their complaint against Defendants Sanofi U.S., Novo Nordisk Inc., and Eli Lilly and Company, allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. Over 29 million people, 9.3% of the country, live with diabetes.¹ A life-threatening disease, many of those with diabetes rely on daily insulin treatments to survive. Interruptions to these regimes can have severe consequences, including sustained damage to the kidneys, heart, nerves, eyes, feet, and skin. Indeed, diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States.²

2. Defendants Sanofi U.S., Novo Nordisk Inc., and Eli Lilly and Company, manufacture insulin used to treat diabetes. Over the course of the last five years, each has raised the publicly-reported, benchmark prices of their respective drugs in an astounding and inexplicable manner. Drugs that used to cost \$25 per prescription now cost between \$300 and \$450 dollars. And in the last five years alone, Sanofi, Novo Nordisk, and Eli Lilly have raised their benchmark prices by over 150%. Some patients now pay almost \$900 dollars per month just to obtain the insulin drugs they need to survive.

¹ *Statistics About Diabetes*, American Diabetes Association (May 18, 2015), <http://www.diabetes.org/diabetes-basics/statistics/>.

² *Chronic Disease Prevention and Health Promotion: Diabetes*, Centers for Disease Control Prevention (July 25, 2016), <https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm>.

3. The impact of these price increases is such that in February 2016, the NEW YORK TIMES published an op-ed written by an endocrinologist, with the headline “**Break Up the Insulin Racket**,” citing some disturbing statistics:³

What makes this so worrisome is that the Big Three have simultaneously hiked their prices. From 2010 to 2015, the price of Lantus (made by Sanofi) went up to 168 percent; the price of Levemir (made by Novo Nordisk) rose by 169 percent; and the price of Humulin R U-500 (made by Eli Lilly) soared by 325 percent.

4. Why has the price of insulin gotten so out of control? Although drug companies usually rely on their research and development costs to rationalize their high drug prices, the manufacturers of insulin admit that their price hikes are unrelated to any jump in production or research and development costs. Instead, these increased benchmark prices are the result of a scheme and enterprise among each Defendant and several bulk drug distributors. In this scheme, the Defendant drug companies set two different prices for their insulin treatments: a publicly-reported benchmark price—also known as the “sticker” price—and a lower, real price that they offer to certain bulk drug distributors.

5. The most important of these bulk drug distributors are entities known as pharmacy benefit managers (“PBMs”).

6. Business is booming for PBMs. Together, the three biggest benefit managers—Express Scripts, CVS Health, and OptumRx—bring in more than \$200 billion a year in revenue. They also control over 80% of the PBM market, covering 180 million insured people.

7. Critical actors in the drug distribution and pricing system, PBMs serve as middlemen between health insurers and drug manufacturers. In this role, PBMs negotiate medicine prices with drug manufacturers on behalf of insurers. Based in part on the prices they

³ Kasia Lipska, *Break Up the Insulin Racket*, NEW YORK TIMES (Feb. 20, 2016), <https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html>.

are able to secure, the PBMs set up tiered formularies for their clients (the health insurers).

Formularies are ranked lists of drugs, where cheaper and more effective medicines are generally placed into lower tiers. The health insurers rely on these formularies to determine how much of their members' drug costs they will cover. Drugs in lower, preferred formulary tiers are cheaper for plan members.

8. Where two medicines are largely interchangeable, a PBM will sometimes exclude the more expensive of the two from its formulary. When a drug is excluded from formulary, health insurers using that formulary will not reimburse their members for purchase of that drug. As a result, formularies enable PBMs to push patients toward certain brands of drugs over others, giving them enormous control over drug purchasing behavior.

9. To secure the PBMs' business, drug companies, including Defendants, offer PBMs prices that are lower than their publicly reported, benchmark prices. Both the PBMs and drug companies refuse to disclose these lower, real prices, labeling them trade secrets. The public-facing justification for such secrecy is: "we do not want our competitors to know the extent of our discounts."

10. But there is a second, more nefarious reason for such concealment. As compensation for their role as negotiator, the PBMs pocket a percentage of the difference between the reported benchmark price and the undisclosed real price they secure. This difference is known as the "spread." As the spread between benchmark and real price widens, so too do the PBMs' cut. PBMs do not disclose this spread because they do not want the public to know their profit margins on medications. The Defendant drug companies do not disclose this spread because they do not want the public to realize that their benchmark prices are wildly inflated.

11. Drug manufacturers, including Defendants, can manipulate this dynamic to the detriment of patient consumers. Where two or more drug manufacturers make largely interchangeable products, those companies would, in an ideal world, continuously drop their real prices to undercut the prices offered by their competitors. But the practice of publicly-publishing one price, while secretly offering another, has enabled drug manufacturers competing within the same therapeutic class to secure PBM business without significantly reducing their real prices. The drug companies know that the PBMs stand to profit from large spreads between real and benchmark prices. Inflated benchmark price increases do not cost the PBMs so long as real prices remain constant (after all, they pay the real price, not the benchmark price). Taking advantage of these realities, drug manufacturers competing with the same therapeutic class have begun to offer the PBMs higher *benchmark prices* instead of lower *real* prices. In other words, instead of marketing lower *real* prices to PBMs, they market the spread *between* prices. The drug manufacturer with the largest spread between benchmark and real price is more likely to secure a PBM's preferred formulary position, and, as a result, the business of that PBM's clients.

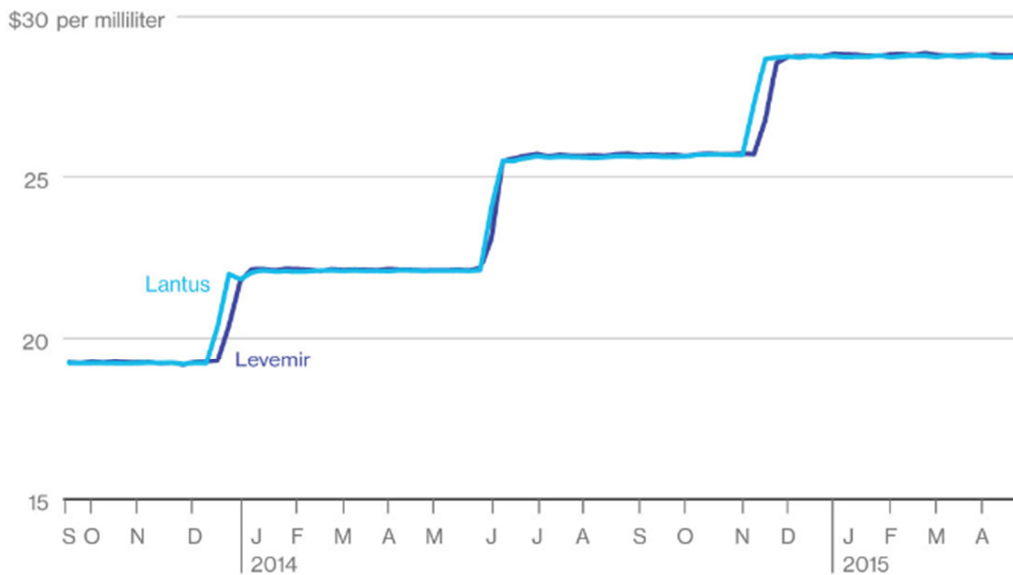
12. This is exactly what has occurred in the market for analog insulin treatments. Defendants Sanofi, Novo Nordisk, and Eli Lilly have offered the three largest PBMs—CVS Health, Express Scripts, and OptumRx—larger spreads as *quid pro quo* for patient business.

13. There are two types of analog insulin: long-acting and rapid-acting. Sanofi and Novo Nordisk both make long-acting analog insulin—Lantus and Levemir, respectively. These drugs are direct competitors in the long-acting insulin category. Novo Nordisk and Eli Lilly compete in the rapid-acting category, manufacturing Novolog and Humalog, respectively.

14. All three Defendants have exponentially raised the benchmark prices of their medicines while maintaining constant (and even slightly lowering) their real prices. This

behavior has enabled them to market larger spreads to the big PBMs in exchange for formulary status. Insidiously, an arms race in the escalation of reported benchmark prices—and consequently spreads—has ensued between Defendants: each Defendant raises its benchmark price just a bit more than its competitors, encouraging the large PBMs to keep its drug on formulary. And Defendants have done so in perfect lock step:

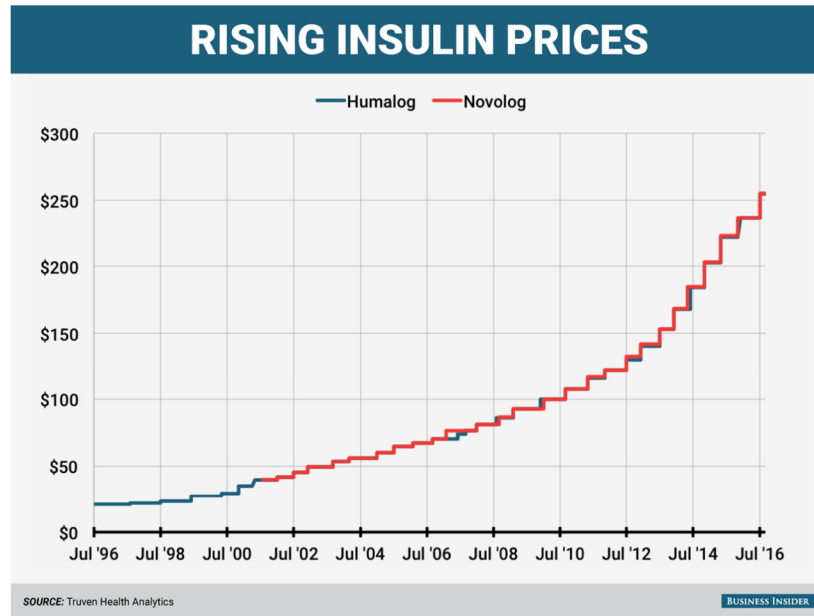
Figure 1: Sanofi and Novo Nordisk Increase Long-Acting Insulin Benchmark Prices in Lock-Step⁴



Source: Bloomberg Intelligence analysis of Symphony Health Solutions data

⁴ Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), <http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep>.

Figure 2: Eli Lilly and Novo Nordisk Increase Rapid-Acting Insulin Benchmark Prices in Lock-Step⁵



15. Eli Lilly basically admitted to the spread pricing scheme in a statement issued in January 2017 from Eli Lilly spokeswoman Julie Williams:

There is a wide and growing discrepancy between the published “list price” Lilly sets and the “net price” that Lilly actually receives.

The list price (also known as the wholesale acquisition cost or WAC) is the price that a manufacturer sets as a starting point for negotiations with federal and state governments, private insurers, and pharmacy benefit managers to gain formulary access. Manufacturers also use list price in negotiations with wholesalers and others involved in the distribution process.

The amount the manufacturer receives after all discounts and rebates are applied is considerably less than the list price. For example, the net price for Humalog – our most commonly used insulin – increased by 4 percent over the five-year period of 2009 to 2014, which is a much smaller increase than what some consumers have experienced.

⁵ Lydia Ramsey, *A 93-year-old Drug that Can Cost more than a Mortgage Payment Tells Us Everything that’s Wrong with American Healthcare*, Business Insider (Sept. 16, 2016), <http://www.businessinsider.com/insulin-prices-increase-2016-9>.

62. When an insured consumer buys a medication from a pharmacy, her insurer pays the pharmacy based on the price its PBM negotiated. In addition to her insurer's payment, the patient usually pays her pharmacy a portion of her medication's cost, out-of-pocket.

63. Insurers get their cash flow from consumers, who purchase insurance coverage. Consumers typically pay their insurers fixed monthly premiums for their health insurance plans. The health insurer relies on these monthly premiums to pay for the prescription drug needs of its members.

64. Pharmacies usually obtain the drugs they distribute from wholesalers or the manufacturers. The wholesalers purchase these drugs directly from the pharmaceutical manufacturers.²⁰

C. Different Prices for Different Players

65. The prices for the drugs distributed in this chain are different for each participating entity. In other words, different actors pay different prices for the same drugs. In this system, only a drug's benchmark price—also known as its Average Wholesale Price (“AWP”)—is publically reported.

66. This price serves as the starting point for negotiations between PBMs and drug manufacturers. PBMs use their formulary control to exact steep discounts from drug companies, known as “rebates.” As previously explained, PBMs create formularies for their health insurer clients and those formularies significantly influence patients' drug purchasing behavior. Health insurers cover all or a portion of their members' drug costs based on whether and where drugs fall on the PBMs' formularies. Sometimes, a drug company will offer one large PBM a deeper price discount than it offers other PBMs in exchange for an exclusive formulary position. The

²⁰ See U.S. Dep't of Health & Human Servs., The Assistant Sec'y for Planning and Evaluation, *Prescription Drug Prices*, 100 (Apr. 1, 2000), <https://aspe.hhs.gov/sites/defaultfiles/pdf/1721711c3.pdf>.

PBM's health insurer clients, who adhere to the PBM's formulary, will then only reimburse their plan members for purchase of the drug with the exclusive position. As a result, PBMs have significant control over what drugs consumers purchase.²¹ They are able to leverage this power to procure deep price discounts.

67. PBMs pass on an undisclosed portion of the discounts or "rebates" they receive to their health insurer clients. Therefore, insurers also pay much lower prices than the benchmark prices.

68. Wholesalers are also able to use their bulk purchasing power to negotiate lower drug prices from the drug companies.

69. In the end, the only actors who actually pay the full drug benchmark prices are consumers who are uninsured or insured but paying for drugs out-of-pocket before they hit their deductibles. Rising benchmark prices also harm patients who pay coinsurance or reach the Medicare Part D "Donut Hole," because these consumers' payments are tied to the drugs' benchmarks prices. As benchmark prices rise, so too do consumer payments.

D. Consumer Drug Costs

70. ***Uninsured.*** Uninsured consumers must pay the full benchmark price every time they pick up their prescriptions. Despite the Affordable Care Act's expansion of Medicaid coverage and establishment of Health Insurance Marketplaces, millions of people—28.5 million in 2015—remain without coverage. This uninsured population is especially concentrated in states that did not take the Medicaid expansion, where diabetes is prevalent. Of the 28.5 million uninsured, reports indicate that 46% tried to get coverage but could not afford it. The uninsured

²¹ See Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 23 Health Affairs w4-504, w4-507 (July 2004).

consideration have been taken into account, discounts that contribute to the net prices, and the net prices to various PBMs, are considered proprietary and confidential by drug manufacturers.

93. The perverse, reverse incentives for larger benchmark prices (and consequent overpayments by consumers) was described recently in a recent report on the drug industry:

At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher benchmark price increases than would otherwise occur, particularly on the eve of a general election. Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [benchmark price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid benchmark price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of benchmark price inflation at least as high, and ideally just a bit higher, than peers'. Durable benchmark price inflation is the natural result. Net price inflation is unaffected, but unit volumes suffer as higher benchmark prices directly impact consumers who have not yet met their deductibles.²⁹

94. This is not the first instance where PBMs have been caught secretly making money on an increase in the spread between benchmark and real prices. In *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.P. 79 (D. Mass. 2007), the court certified a class alleging that McKesson, a wholesaler, and First Data, a drug price publisher, engaged in a scheme to inflate the benchmark prices of brand name drugs. McKesson asserted that a class could not be certified because PBMs had become aware of the phony increase in the spread, and promptly acted to offset the spread by vigorously seeking rebates for its health insurer clients. However, part of the evidence Judge Saris relied upon in rejecting this

²⁹ Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC, 36 (Oct. 5, 2016).

contention was evidence showing that the PBMs pocketed a portion of the increase in the spread at the expense of consumers and health insurers:

Because these PBMs benefited from the increased [benchmark price] spreads perpetuated by the Scheme, Plaintiffs argue that they had no incentive to inform [third party payers (*i.e.* health insurers)] of the inflated AWP, let alone fiercely compete to mitigate any damage. As proof, Plaintiffs quote an April 26, 2002 internal ESI e-mail, sent around the same time as the ESI letter, that states that “the AWP increases being pushed through by First Data Bank [are] having a very favorable impact on our mail margins.” The e-mail goes on to state, “Our clients will not be sympathetic to our financial situation since we [will have benefited] from the AWP increase in the mail and they hired us to control drug trend.” The e-mail includes a handwritten note, in response, “Let’s put a lid on it and not make it a big deal.”³⁰

95. As noted above, the PBMs can use the phony benchmark prices to their advantage. As a result of this scheme, the PBMs gain the opportunity to exact larger rebate profits, without paying any more money for the drugs themselves. And all the while, the PBMs can boast of the “increased rebates” they have achieved, when, in reality, the “discount” they have achieved is simply a reduction off an artificially inflated benchmark price. The drug maker benefits from this scheme by maintaining a formulary position it otherwise may have lost.

96. The losers in this scheme are patients. When drug companies inflate benchmark prices so that they can offer PBMs larger spreads, they harm uninsured patients, who must pay benchmark prices out-of-pocket. They also hurt insured consumers in high-deductible plans who must pay the artificially inflated benchmark prices until they hit their deductibles. Consumers paying coinsurance suffer because their coinsurance payments rise with benchmark price increases. So too do Medicare Part D patients, especially when they reach the Donut Hole.

³⁰ *New England Carpenters Health Benefits Fund v. First Data Bank, Inc.*, 248 F.R.D. 363, 367 (D. Mass 2008) (internal citations omitted).

190. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and members of the class. Novo Nordisk and the PBMs calculated and intentionally crafted the Levemir and Novolog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs and members of the class who would be over-billed for Levemir and Novolog. In designing and implementing the scheme, at all times Novo Nordisk was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting benchmark prices and establishing rebates.

191. By intentionally and artificially inflating the Levemir and Novolog benchmark prices, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Novo Nordisk and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

192. Novo Nordisk's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Novo Nordisk was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Novo Nordisk has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Levemir/Novolog Pricing Enterprise.

results affecting similar victims, including Plaintiffs and members of the class. Eli Lilly and the PBMs calculated and intentionally crafted the Humalog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs and members of the class who would be over-billed for Humalog. In designing and implementing the scheme, at all times Eli Lilly was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting benchmark prices and establishing rebates.

233. By intentionally and artificially inflating the Humalog benchmark price, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Eli Lilly and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

234. Eli Lilly's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Eli Lilly was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Eli Lilly has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Humalog Pricing Enterprise.

235. The pattern of racketeering activity alleged herein and the Humalog Pricing Enterprise are separate and distinct from each other. Likewise, Eli Lilly is distinct from the Humalog Pricing Enterprise.

275. By intentionally and artificially inflating the Lantus benchmark price, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Sanofi and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

276. Sanofi's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Sanofi was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Sanofi has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Lantus Pricing Enterprise.

277. The pattern of racketeering activity alleged herein and the Lantus Pricing Enterprise are separate and distinct from each other. Likewise, Sanofi is distinct from the Lantus Pricing Enterprise.

278. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

I. Sanofi's Use of the U.S. Mail and Interstate Wire Facilities

279. The Lantus Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Lantus benchmark price; the payment from Sanofi to the PBMs of substantial rebates off of the benchmark price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.